

## HUMAN SERVICES BOARD

# INTRODUCTION

## FINDINGS OF FACT

2. The only difference between the two drugs is that Suboxone contains an additional ingredient, naloxone, which limits its potential for misuse and misappropriation.

Because of this, it is the "preferred" drug approved by OVHA in the treatment of opiate addiction (see *infra*).

3. The petitioner has been using Subutex, apparently at his own expense, since September 2008. Several prior requests to OVHA for approval based on self-reported relatively minor symptoms from taking Suboxone (e.g. "bad taste in his mouth") were denied.

4. Following the petitioner's appeal, filed in December 2008, the petitioner's treating physician submitted the following in a letter dated January 16, 2009:

(Petitioner) as you know is on Subutex because of narcotic addiction and chronic pain. He is intolerant to Suboxone. He is contesting your decision about whether to pay for Subutex or not. The basis for his intolerance was documented in medical records by (Dr.) from Waterbury, Vermont. (Dr.) noted in his chart that (petitioner) self-reported that he had nausea from the pill. This did not satisfy the Board's requirement, as he had to have a true allergy or be pregnant.

I brought (petitioner) into my office this past week and I had him put an 8 mg./2mg. Suboxone tablet under his tongue, and I sat with him while it was dissolving. It took several minutes, but before the pill was totally dissolved, he developed a violent vomiting reaction where he got up out of his chair and ran over to the sink and started vomiting. He fell to the floor at one point. I helped him up. His blood pressure and pulse remained stable. After about 10 minutes, he left the office and was fine. However, in my medical opinion, (petitioner) has a clear physical intolerance to this medicine, and I think he deserves to have the Subutex paid for by the State.

5. In a revised decision, dated January 26, 2009, OVHA's medical director again denied prior approval with the following rationale:

I cannot issue an exception in this case as the letter describes a reaction to Suboxone within minutes that is very dramatic and not reported previously to the manufacturer. The reaction seems unlikely to be caused by the medicine itself in such a rapid amount of time, unaccompanied by a physiological change in the patient's vital signs. It seems to me to be more consistent with a psychological reaction, rather than a GI intolerance to the medication.

6. On the hearing officer's advice suggesting a clinical trial of Suboxone, the petitioner submitted a written response from his treating physician, dated April 6, 2009 that included the following:

I would beg the state's permission to please pay for (Subutex). Side effects of medication are common and we cannot stop medications when they occur. For instance, the over-the-counter medication called ibuprofen. This can cause bleeding ulcers in the stomach. That is not an allergy but is a side effect and we stop the drug because of it. The same can be said for the Suboxone causing the nausea and vomiting. Again, as described in a previous letter, we did a trial in my office and I saw firsthand the nausea and vomiting.

7. In a written response dated April 20, 2009 (allowed by the hearing officer) OVHA's attorney represented that the medical director was not convinced that the reaction described by the petitioner's physician was not "histrionics", and that OVHA's position is that "a suitable,

safe trial of Suboxone for (petitioner) would consist of giving him the drug and having him stay in a room with a nurse taking his vital signs and monitoring him closely for several hours", so that "it could be clinically evaluated whether (petitioner's) reaction, if any, was believable or not."

8. There is no question in this case that the petitioner's treating physician is clearly convinced that the petitioner is truly intolerant of Suboxone. OVHA does not dispute that the petitioner had the vomiting reaction to Suboxone as observed and described (above) by his doctor. The issue, as framed by OVHA, is whether the petitioner essentially tricked his doctor with this reaction. However, based on the above evidence, it certainly cannot be concluded that the petitioner's doctor lacks the training or medical expertise to detect whether his patient legitimately suffered the adverse reaction he observed.

ORDER

OVHA's decision denying prior approval of Subutex is reversed, effective January 16, 2009.

REASONS

The Vermont Health Assistance Program (VHAP) generally covers payment for medications that are medically necessary. W.A.M. §§ 107 & 4005B. As a general matter, the Board has upheld OVHA's criteria for the prior approval of drugs to treat opiate dependency (Subutex and Suboxone). See Fair Hearing No. B-11/08-504. There is no dispute that OVHA's criteria for prior approval for these drugs are:

- Diagnosis of opiate dependence confirmed (will not be approved for the alleviation of pain).

AND

- Prescriber has a DATA 2000 waiver ID number ("X-DEA license") in order to prescribe.

AND

- If Subutex is being requested,  
~Patient is either pregnant. . .

OR

- ~Patient has a documented allergic reaction to naloxone supported by medical record documentation.

Based on the medical evidence cited above, it must be concluded that the petitioner met the above criteria as of January 16, 2009, the date of the letter from his treating physician observing, documenting, and evaluating his vomiting reaction to Suboxone. Prior to the most recent (April 6,

2009) letter from the petitioner's doctor, the hearing officer agreed (and so advised the parties) that he felt a clinical trial of Suboxone may have been warranted. However, it is now clear that the petitioner's doctor is of the opinion that such a trial is not only inappropriate but also medically contraindicated.

As a general matter, OVHA does not appear to dispute that a "side-effect" in an individual patient, however atypical of the medication, would constitute an "allergic reaction" within the meaning of the above criteria. There is also no dispute in this case that the petitioner's doctor is fully licensed and qualified under the regulations to treat drug addiction. OVHA's position at this point appears to be based solely on its doubts regarding the *competence* of the petitioner's doctor to medically judge and evaluate his own observations. OVHA is, of course, free to act on such concerns in this, or any other, case through professional licensing and oversight procedures. It is inappropriate, however, for OVHA to place the additional burden on any individual patient *in the prior approval process* of essentially proving that his doctor is *not* incompetent.

Inasmuch as the medical evidence in this case clearly establishes that the petitioner met the above criteria for

prior approval of VHAP coverage for Subutex as of January 16, 2009, OVHA's decision denying prior approval must be reversed as of that date.

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